

AMENDMENTS TO THE DRAWINGS

Please replace drawing sheet number 2/3 and 3/3 with the attached replacement sheets 2/3 and 3/3.

REMARKS

Status of the Claims

Claims 1-10 are currently pending in the application.

Claims 1, 3, 6, 7, 9 and 10 are amended with entry of this amendment.

Claim 8 is cancelled with entry of this amendment.

Claims 1-7 and 9-10 remain under consideration with entry of this amendment.

Summary

Claims 1-10 are pending in the application and were examined in the Office Action dated 29 September 2006. In the Office Action, the following objections/rejections have been raised: **(a)** the drawings have been objected to under 37 CFR §1.84, paragraphs 4 and 5, on the basis of various informalities; **(b)** the drawings have been objected to under 37 CFR §1.83(a) on the basis of informalities; **(c)** the specification has been objected to under 37 CFR §1.75(d)(1) on the basis of improper antecedent basis; **(d)** claims 1-10 have been objected to as informal; **(e)** claims 1-10 stand rejected under 35 U.S.C. §112, first paragraph, as nonenabled; **(f)** claims 2, 8 and 9 stand rejected under 35 U.S.C. §112, second paragraph, as indefinite; and **(g)** claims 1-10 stand rejected under 35 U.S.C. §103(a) as unpatentable over U.S. Patent No. 6,530,875 to Taylor et al. ("Taylor") in view of U.S. Patent No. 6,270,472 to Antaki et al. ("Antaki"). Applicants respectfully traverse the objections to the specification, drawings and claims, and all pending claim rejections for the following reasons.

Overview of the Amendments

Applicants, by way of this Response, have amended the specification to correct certain typographical errors, submitted replacement drawings to correct certain related typographical errors, and have amended claims 1, 3, 6, 7, 9 and 10 in order to recite the invention with greater specificity.

More particularly, paragraph [0047] has been amended to correct a typographical error in the reference character for the bottom assembly. Paragraph [0049] has been

amended to correct a typographical error (to change “plug” to “plunger”). Paragraphs [0053], [0055], [0056], [0058], and [0059] have been amended to correct typographical errors in the reference characters used in Figures 2 and 4 (reference characters 30, 32, 34, 36, 38, 40, 42, 44, 46 and 48 have been changed to 130, 132, 134, 136, 138, 140, 142, 144, 146 and 148, respectively), and to correct the typographical error in the units from “lbf” to N (Newtons). Support for these amendments to the specification can be found in the specification and drawings as originally filed. Accordingly, no new matter has been added by way of these amendments to the specification, and the entry thereof is respectfully requested.

In addition, applicants have provided herewith replacement sheets 2/3 and 3/3 containing amendments to Figures 2 and 4. More particularly, in Figure 2, reference characters 30, 32, 34, 36, 38, 40, 42, 44, 46 and 48 have been changed to 130, 132, 134, 136, 138, 140, 142, 144, 146 and 148, respectively, in order to conform to the amendments to the specification. In addition, reference character 54 has been deleted from the figure pursuant to 37 CFR §1.84(p)(5). In Figure 4, reference character 30 has been changed to 130, also in order to conform to the amendments to the specification. Accordingly, no new matter has been added by way of these amendments to the figures, and the entry of replacement sheets 2/3 and 3/3 is respectfully requested.

Finally, applicants, also by way of this Response, have cancelled certain claims and presented minor amendments to other claims. In particular, claim 8 has been cancelled without prejudice and disclaimer. Cancellation of this claim is not in acquiescence to any pending grounds of rejection, and applicants expressly reserve their right to bring the claim again in another related application. Claim 1 has been amended to recite the invention with greater specificity. In particular, claim 1 has been amended to overcome the objections raised by the Office regarding antecedent basis for “said device” and “said device function” and to remove certain typographical errors. In addition, the limitation expressly recited in claim 3 has been removed from (base) claim 1, and a limitation expressly reciting the actuating mechanism has been added to claim 1. Claim 3 has been amended to properly recite the first and second resistive load levels; claim 6 has been amended to recite the resistive load in Newtons (N); claim 7 has been amended to

recite that the device to be activated is activated when present in the recited apparatus; claim 9 has been amended to properly recite the retaining mechanism; and claim 10 has been amended to overcome the objection raised by the Office regarding antecedent basis for “said device function”. Support for the amendments to claims 1, 3, 6, 7, 9 and 10 can be found throughout the specification and claims as originally presented. Accordingly, no new matter has been added by way of these amendments to the claims, and the entry thereof is respectfully requested.

The Objection under 37 CFR §1.84(p)(4)

The drawings were objected to under 37 CFR §1.84(p)(4) on the basis that certain reference characters were used to designate more than one element in the figures. Corrected drawing sheets in compliance with 37 CFR §1.121(d) were required.

In response, applicants have submitted herewith replacement sheets 2/3 and 3/3 that contain amendments to Figures 2 and 4, and have further entered amendments to the specification in order to correct the errors in the reference characters. Reconsideration and withdrawal of the objection to the drawings under 37 CFR §1.84(p)(4) is thus respectfully requested.

The Objection under 37 CFR §1.84(p)(5)

The drawings were objected to under 37 CFR §1.84(p)(5) on the basis that they include a certain reference character not mentioned in the specification. Corrected drawing sheets in compliance with 37 CFR §1.121(d) were required.

In response, applicants have submitted herewith replacement sheet 2/3 that contains amendments to Figure 2 removing the subject reference character (54) from the drawings. Reconsideration and withdrawal of the objection to the drawings under 37 CFR §1.84(p)(5) is thus respectfully requested.

The Objection under 37 CFR §1.83(a)

The drawings were objected to under 37 CFR §1.83(a) on the basis that the drawings must show every feature of the invention specified in the claims. In particular,

the Office has objected that the “retaining mechanism” must be shown in the drawings or the feature cancelled from the claims. Office Action at page 3. Corrected drawing sheets in compliance with 37 CFR §1.121(d) were required. Applicants respectfully traverse the objection for the following reasons.

Applicants draw the Office’s attention to Figures 2 and 3, as well as the supporting disclosure in paragraphs [0055] and [0056], wherein two retaining mechanisms (element 60 in Figure 2 and element 84 in Figure 3) are shown in the drawings. Reconsideration and withdrawal of the objection to the drawings under 37 CFR §1.83(a) is thus respectfully requested.

The Objection under 37 CFR §1.75(d)(1)

The specification was objected to under 37 CFR §1.75(d)(1) on the basis that the specification fails to provide proper antecedent basis for the claimed subject matter. In particular, the Office has objected that “the disclosure does not mention resistive load means comprising a spring where the spring has a first resistive load level and a second load level [and] does not mention a resistive load of about 1 to 30 lbft.” Office Action at page 4. Applicants respectfully traverse the objection for the following reasons.

Initially, applicants draw the Office’s attention to the amendments to claim 6, submitted herewith, wherein the language has been amended to recite first and second resistive loads of about 1N and 5N, respectively. Support for these load amounts can be found at paragraph [0023] and ([0053] as amended) of the specification. With regard to the objection regarding a spring having two resistive load levels, applicants note that the claim element recites a “resistive load means” that is disclosed in the application to include a set of springs (see paragraph [0053]), a single load member (paragraph [0054] and Figure 3), and combinations of various elements such as springs and various obstructions (paragraph [0054]). Applicants submit that the term “means” should not be construed by the Office as requiring a single element due to the disclosure of various single and multiple element means in the specification. Reconsideration and withdrawal of the objection under 37 CFR §1.75(d)(1) is thus respectfully requested.

The Office has also objected to the specification under 37 CFR §1.75(d)(1) on the basis that reference characters 30 and 18 have been inconsistently used in specification, and that the reference to the unit “lbf” is unclear. In response, applicants draw the Office’s attention to the amendments to the specification submitted herewith, wherein the “lbf” unit has been replaced with the correct N (Newton) unit used in other portions of the specification, and wherein the typographical errors with reference characters 30 and 18 have been corrected. Reconsideration and withdrawal of the objection under 37 CFR §1.75(d)(1) is thus respectfully requested in light of the subject amendments.

The Claim Objections

Claims 1-10 have been objected to as informal on the following bases: recitation of limitations “said device” and “said device function” without earlier positive recitation; and “said second resistive load” and “said first resistive load” again without proper antecedent basis. Correction was required.

In response, applicants draw the Office’s attention to the amendments to the claims submitted herewith, wherein the claims have been amended to provide proper antecedent basis for the various claim limitations identified by the Office. Reconsideration and withdrawal of the objection to claims 1-10 is thus respectfully requested in light of these subject claim amendments.

The Rejection under 35 U.S.C. §112, first paragraph

Claims 1-10 were rejected under 35 U.S.C. §112, first paragraph, on the basis of enablement. In particular, the Office has objected that “it is unclear how the device function is being activated by applying sufficient force to overcome [resistive levels, and] the specification does not clearly describe what the function of the device is and how the activation of the device is accomplished by pushing, pulling or turning a portion of the device when the device is in the claimed apparatus.” Finally, the Office has objected “it is unclear what is meant by a resistive load of 0.5 to 3 lbft or 1 to 30 lbft.” Office Action at page 5. Applicants respectfully traverse the rejection for the following reasons.

Initially, applicants draw the Office's attention to the amendments to the claims and specification wherein the units have been corrected to specify N (Newtons). With regard to the other objections, applicants draw the Office's attention to paragraph [0024] wherein it is disclosed that an implantable drug delivery device can be activated by the recited apparatus using electrical or electromagnetic forces to open or close a channel on the device. The disclosure goes on to discuss the use of a solenoid or inductive coil that can be actuated by applying force to the device within the apparatus (e.g., physical contact of circuitry as the device moves through the apparatus). In paragraph [0025] yet another example is provided wherein an electrical circuit on an electrochemical pump device can be actuated (opened or closed) using movement of the device through the apparatus. Furthermore, in paragraph [0049], a drug delivery device is disclosed having a valve mechanism that can be opened simply by physical contact (depressing a plunger relative to a housing) again as the device moves within the apparatus. In paragraph [0052], applicants disclose still further examples for activation of a device within the recited apparatus, wherein the trocar itself is configured to open an orifice in the device (implant), depress a button, actuate an electronic switch, or break a septum or seal on the device (implant). All of these actions can easily be carried out with simple translational movement of the device within the recited apparatus. Accordingly, contrary to the Office's assertions, applicants submit that there is more than sufficient disclosure provided by the specification regarding actuation of a device by movement within the recited apparatus. Reconsideration and withdrawal of the rejection of claims 1-10 under 35 U.S.C. §112, first paragraph, is thus earnestly solicited.

The Rejection under 35 U.S.C. §112, second paragraph

Claims 2, 8 and 9 were rejected under 35 U.S.C. §112, second paragraph, on the basis of indefiniteness. In particular, the Office has objected that "in claim 2, it is unclear how the resistive load means comprising a spring can have a first and second resistive load level", and further that "in claim 8, it is unclear if the implant-retaining member [refers to the element from claim 1]." Office Action at page 6. Applicants respectfully traverse the rejection for the following reasons.

Initially, applicants draw the Office's attention to the amendments to the claims submitted herewith, wherein claim 8 has been cancelled, rendering the rejection of that claim moot. With regard to the objection regarding a resistive load means comprising a single spring with multiple resistive loads, applicants direct the Office's attention to the disclosure in their specification that a "resistive load means" can include a set of springs (see paragraph [0053]), a single load member (paragraph [0054] and Figure 3), and combinations of various elements such as springs and various obstructions (paragraph [0054]). Applicants submit that the term "means" should not be construed by the Office as requiring a single element due to the disclosure of various single and multiple element means in the specification. Reconsideration and withdrawal of the rejection of claims 2 and 9 under 35 U.S.C. §112, second paragraph, is thus earnestly solicited.

The Rejection under 35 U.S.C. §103

Claims 1-10 stand rejected under 35 U.S.C. §103(a) as obvious over Taylor in view of Antaki. Applicants respectfully traverse the rejection for the following reasons.

When considering the patentability of claims under Section 103, the following tenets of patent law must be adhered to: (a) the claimed invention must be considered as a whole; (b) the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (c) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (c) reasonable expectation of success is the standard with which obviousness is determined. *Hodosh v. Block Drug Co., Inc.*, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986). In addition, the prior art (i.e., the art or the combination of art) must itself provide "motivation, suggestion, or teaching of the desirability of making the specific combination that was made by applicant." See, *In re Kotzab*, 55 USPQ2d 1313, 1316 (Fed. Cir. 2000) and *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, 75 USPQ2d 1051, 1054 (Fed. Cir. 2005). The issue of the proper source for finding sufficient motivation, suggestion or teaching has been considered numerous times by the Federal Circuit and other courts, and the case law is consistent in demanding that the source is the prior art itself and not applicant's own disclosure (see, e.g., *In re Vaeck*, 20 USPQ2d

1438, 1442 (Fed. Cir. 1991) and *Noelle v. Liderman*, 69 USPQ2d 1508, 1516 (Fed. Cir. 2004)).

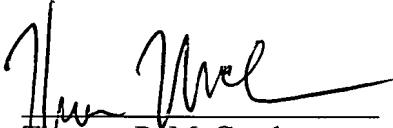
Applicants disclose and claim an apparatus that can be used to simultaneously implant and actuate a drug delivery device. In the present rejection, the Office has merely found certain elements of applicant's claimed apparatus from different pieces of cited art and then concluded that since most of the elements can be found individually in this manner, it must have been obvious to create applicants' device. Importantly, neither of the cited references discloses, teaches or so much as suggests the simultaneous activation of a device, rather these references are solely directed to the implantation of devices. A mere conclusory statement in an Office Action that this function could be expected cannot form the basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, F.3d 1338, 1343-44 (Fed. Cir. 2002). In addition, the mere fact that portions of various prior art disclosures can be combined in a certain way does not render the resultant combination obvious unless the prior art also suggests all of the recited elements of a claim and the desirability of that combination. *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 2000). Thus, the Office's rejection is improper since the prior art must itself provide sufficient motivation, suggestion, or teaching of the desirability of making applicant's specific combination. *In re Vaeck*, 20 USPQ2d 1438, 1442 (Fed. Cir. 1991); *In re Grabiak*, 769 F.2d 729 (Fed. Cir. 1985); *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *In re Ochiai*, 71 F.3d 1565 (Fed. Cir. 1995). For all of these reasons, then, the rejection of claims 1-10 under 35 U.S.C. §103(a) is improper. Reconsideration and withdrawal of the rejection is earnestly solicited.

CONCLUSION

Applicants submit that the pending claims define an invention that is both novel and nonobvious over the cited art, and thus all claims are in condition for allowance. Acknowledgement of this by the Office in the form of an early allowance is thus respectfully requested. In addition, if the Examiner contemplates other action, or if a

telephone conference would expedite allowance of the claims, applicants invite the Examiner to contact the undersigned at (408) 777-4915.

Respectfully submitted,



Thomas P. McCracken
Registration No. 38,548

Date: 29 March 2007

For and on behalf of
DURECT CORPORATION
2 Results Way
Cupertino, CA 95014
Phone: (408) 777-4915
Fax: (408) 777-3577